IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION	Master Docket: Misc. No. 21-1230
This Document Relates to: All Actions	MDL No. 3014

MEMORANDUM OPINION

I. Introduction

The Special Master[1] issued a report and recommendation ("R&R") (ECF No. 2271), on a motion to dismiss the Master PI complaint filed by defendant Philips RS North America, LLC ("Respironics").[2] Pending before the court are: (1) (ECF No. 2312) Plaintiffs' motion to modify and/or clarify, in part, the Special Master's R&R, which contains a motion for leave to amend plaintiffs' Amended Master Long Form and Short Form Complaints for Personal Injuries and Damages (the "Master PI complaint"); (2) (ECF No. 2313) Plaintiffs' objections to the R&R about the Master PI complaint; and (3) (ECF No. 2315) Respironics' objections to the R&R

[1] On January 18, 2023, the court appointed the Honorable Thomas I. Vanaskie ("Special Master") to serve as a special master ("Special Master") pursuant to Federal Rule of Civil Procedure 53 (ECF No. 1434).
[2] The motion to dismiss and objections to the R&R were filed only on behalf of Respironics. There was no motion filed on behalf of the other defendants. In Respironics' brief, there was a footnote stating that the "Philips Defendants join in the arguments for dismissal made by Respironics in its Rule 12(b)(6) briefs . . . , all of which also apply to the Philips Defendants." (ECF No. 1359 at 15 n.3). Plaintiffs recognize that the Philips Defendants joined the motion to dismiss (ECF No. 2313 at 5 n.1) and did not object to that joinder. The rulings on the motion to dismiss, therefore, will apply to all defendants named in the relevant counts.

about the Master PI complaint.[3] The objections and underlying motions are fully briefed and ripe for disposition.

II. Factual and Procedural Background

This is a multi-district litigation ("MDL") involving CPAP, Bilevel PAP, and mechanical ventilator products. On October 24, 2022, pursuant to the parties' agreement and pretrial order #28 (ECF No. 783), plaintiffs filed an amended Master PI complaint (ECF No. 834). The long form Master PI complaint is 190 pages long and has 164 exhibits. The master complaint anticipates that individual personal injury plaintiffs will also file short form complaints, which will incorporate the allegations in the master complaint, and Plaintiff Fact Sheets (ECF No. 871).

On January 6, 2023, Respironics filed a motion to dismiss the Master PI complaint in its entirety, with brief in support (ECF Nos. 1345, 1346). Plaintiffs filed a brief in opposition to the motion (ECF No. 1643) and Respironics filed a reply (ECF No. 1827). On January 31, 2023, the court referred Respironics' motion to dismiss the Master PI complaint to the Special Master for report and recommendation.[4] The appointment order specified, in relevant part, that: (1) the failure to file a timely objection shall constitute a waiver of any objection; and (2) the Special Master's R&Rs will be reviewed by the court de novo. (ECF No. 1434 ¶¶ 16, 17).

The Special Master heard in-person oral arguments on July 10-11, 2023, which the court attended. On September 28, 2023, the Special Master filed a 160-page R&R (ECF No. 2271), which recommended that Respironics' motion to dismiss the Master PI complaint be granted in

[3] The parties' objections to the Special Master's R&R about the medical monitoring complaint will be addressed in a separate opinion and order.

[4] The Special Master performed outstanding service in this massive undertaking, which involved numerous legal theories and necessitated surveys of the law of all 50 states. Plaintiffs expressed their appreciation for the Special Master's thoughtful analysis and acknowledged that he reached the correct determination on most claims (ECF No. 2313 at 5). Respironics, while preserving its positions set forth in the motion to dismiss the Master PI Complaint, asserted only 10 narrowly targeted objections to the R&R. The court deeply appreciates the efforts of the Special Master.

part and denied in part. Both sides filed timely objections to the R&R. Plaintiffs filed a motion to modify or clarify the R&R, which includes a request for leave to file a second amended complaint.

Discussion

A. Positions of the parties

Citing the liberal standard set forth in Federal Rule of Civil Procedure 15, plaintiffs seek to amend the Master PI complaint in several respects to respond to or clarify matters raised in the R&R. Specifically, plaintiffs seek leave to file an amended complaint to address the following topics:

1. To clarify that their common law fraud claim (count XIII) is based on the theory of fraudulent omission, not commission, and to plead additional facts obtained during discovery in support of their fraudulent omission theory (ECF No. 2313 at 6-7);
2. To distinguish their theories of negligent failure to recall and negligent execution of the recall, by pleading those theories in separate counts. The two theories were confusingly intertwined in count VI of the Master PI complaint. Both plaintiffs and Respironics agree that the theories should be separately pleaded and analyzed (ECF No. 2313 at 8-9; ECF No. 2315 at 7);
3. With respect to subsumption, plaintiffs aver they can eliminate confusion by specifically asserting separate claims under each state's relevant product liability law to replace individual counts that were deemed subsumed (ECF No. 2313 at 10); and
4. With respect to states that have multiple consumer protection laws, plaintiffs would plead each asserted law as a separate count.

Plaintiffs represent that the amendment "would only clarify or supplement issues and claims the parties have already contemplated and briefed." (ECF No. 2313 at 17). Respironics does not contest plaintiffs' ability to file an amended complaint at an appropriate time, but argues that the pending motion is premature (because the court has not ruled on the pending motion to dismiss) and improper (because Plaintiffs did not submit a proposed amended pleading) (ECF No. 2372).

Respironics maintains that the Master PI complaint should be dismissed in its entirety, but asserts only 10 targeted objections to the R&R:

1. Respironics agrees that the negligent failure to recall and negligent execution of the recall theories should be disaggregated and analyzed separately, particularly with respect to primary jurisdiction and preemption.[5] Respironics maintains that both claims should be dismissed, albeit for different reasons;
2. Respironics contends that the negligent failure to recall theory is not cognizable under Illinois and Oklahoma law;
3. Respironics challenges the recommendation on negligence per se claims under Arkansas, Alabama and Maine law and asserts that the Special Master did not address their challenge to negligence per se claims under 7 other states' laws;
4. Respironics contends the negligent misrepresentation claim is not cognizable under Minnesota law;

[5] The issues whether primary jurisdiction or preemption will necessitate the dismissal of these claims will need to be reasserted in any motion to dismiss an amended master PI complaint. The court notes that the special master recommended that Respironics' motion to dismiss negligence, warranty, fraud, consumer protection and unjust enrichment claims based on implied preemption be denied (ECF No. 2271 at 14-23). Respironics, while preserving for appeal its arguments with respect to all those claims, filed objections only with respect to the negligent failure to recall and negligent execution of the recall claims. The court adopts the R&R with respect to all other legal theories and Respironics will not be permitted to reassert preemption with respect to those theories in a renewed motion to dismiss. Respironics' arguments raised in its motion to dismiss the Master PI Complaint are preserved for appeal. The primary jurisdiction defense relates only to the negligent recall claim and can be reasserted by Respironics.

5. Respironics argues that consumer protection claims must be pleaded with particularity pursuant to Federal Rule of Civil Procedure 9(b);
6. Respironics argues that a prescription medical device is not a good for "personal, family or household uses," as required by the consumer protection laws of 24 states;
7. With respect to express and implied warranty and consumer protection claims, Respironics argues the failure to plead presuit notice;
8. With respect to the negligent manufacturing and strict liability – manufacturing defect claims, Respironics argues that the only alleged manufacturing error involves the Trilogy EVO, a device which is not at issue in this litigation;
9. Respironics contends that the express warranty claim should be dismissed because the only claim within the scope of the warranty involves the manufacturing of the Trilogy EVO device; and
10. Respironics argues that Restatement (Second) of Torts § 402(A), comment k, bars strict liability claims against medical device manufacturers under Pennsylvania law.

B. Leave to amend will be granted

Federal Rule of Civil Procedure 15 adopts a liberal amendment policy. This court has discretion whether or not to require the proposed amended complaint to be attached to the motion. *See In re Allergan Erisa Litig.*, 975 F.3d 348, 358 n. 16 (3d Cir. 2020) ("[B]y recognizing that a district court acts within its discretion when it denies leave to amend where no proposed amendment is included in the request we do not mean to imply that a court necessarily abuses its discretion by allowing a party to amend without having submitted a proposed amendment."). The underlying rationale for requiring the proposed amended complaint to be

attached is to allow the court to determine whether amendment would be frivolous. *Id.* at 356 n.13. Here, both parties recognize that certain aspects of the contemplated amendment would not be frivolous.

In this complex matter, amendment of the personal injury master complaint makes eminent sense. Plaintiffs represent that they can fix several of the deficiencies identified by the Special Master (ECF No. 2313 at 17). For example, plaintiffs may be able to moot the recommended dismissal of the common law fraud claims by pleading additional facts they obtained during discovery. Both parties agree that the negligent failure to recall and negligent execution of the recall claims should be disaggregated and separately pleaded and analyzed.

Plaintiffs asserted only "generic" claims based on consumer protection statutes in the Master PI complaint. Respironics asserted numerous defenses to the consumer protection claims on which state law varies. The lack of clarity with respect to the various state consumer protection laws can be remedied by requiring plaintiffs to plead each relevant statute in a separate count, so that Respironics' defenses can be tailored to the actual statutes being asserted (ECF No. 2313 at 10) and any motion to dismiss can be precisely targeted and analyzed.[6]

In sum, plaintiffs' request for leave to file an amended master Master PI complaint will be granted, consistent with plaintiffs' representation that they will only clarify and supplement issues and claims that the parties have previously contemplated and briefed (ECF No. 2313 at 17). The time invested in precisely determining which legal theories are cognizable will prevent the expenditure of unnecessary time and money during discovery.

The efforts of the parties and Special Master have not been in vain. The disputes have been significantly narrowed. For claims which the Special Master recommended the motion to

[6] In doing so, plaintiffs should consider whether the claims sound in fraud and must meet the Rule 9(b) pleading standard (ECF No. 2315 at 12 & n.8).

dismiss be granted and plaintiffs did not object to that recommendation, plaintiffs must not assert those claims in the amended master Master PI complaint. For claims which the Special Master recommended the motion to dismiss be denied and Respironics did not object to that recommendation, Respironics must not reassert its contentions in any motion to dismiss the amended master Master PI complaint. The failure to raise timely objections to the R&R waived the parties' respective right to object with respect to those issues. (ECF No. 1434 ¶ 16). The court reviewed the R&R and adopts the recommendations of the R&R as the opinion and order of the court with respect to all issues to which the parties did not assert a specific objection. The parties' appellate rights will be preserved, and those issues need not be repeated.

Respironics' motion to dismiss the fraud claims, the negligent failure to recall and negligent execution of the recall claims and the consumer protection claims, as pleaded, will be granted without prejudice to plaintiffs' ability to file an amended master PI complaint within 14 days of this opinion and order. The court will reserve further comment on those claims and defenses, including primary jurisdiction, preemption and subsumption.[7] It is expected that an amended complaint and renewed briefing will significantly narrow and clarify the disputes with respect to those theories.[8]

An amended Master PI complaint will supersede the original complaint and the new complaint will become the operative pleading. *Garrett v. Wexford Health*, 938 F.3d 69, 82 (3d Cir. 2019). Respironics will have an opportunity to file a motion to dismiss any revised or supplemented portions of the amended master complaint, consistent with this opinion. Any

[7] The existing briefing of the primary jurisdiction and preemption issues did not separately address the negligent failure to recall and negligent execution of the recall theories. The subsumption issue cannot be resolved because it may vary from state to state and plaintiffs pleaded only a generic consumer protection theory.

[8] For example, for the consumer protection claims, the parties should address what constitutes "presuit notice" in the context of a master complaint in an MDL. (ECF No. 2129 at 164-67).

motion to dismiss will be referred to the Special Master for another R&R. As part of that referral, the Special Master may address any claims which the parties identified as needing a more specific ruling in the original R&R.

C. Certain legal issues will be resolved

To promote the efficient progress of this litigation, the court will address certain disputed legal issues that may be resolved on the current record.

1. Negligence per se (Alabama, Arkansas, Maine)

Respironics argues that the R&R should have recommended that its motion to dismiss the negligence per se claims under Alabama, Arkansas and Maine law be granted; and that the Special Master failed to consider its challenge to the negligence per se claims under the laws of 7 other states.[9] Plaintiffs, in response, point out that Respironics' original brief addressed negligence per se claims for 26 states in a single paragraph. Plaintiffs also note that the real dispute is whether negligence per se can be pleaded as a distinct legal theory, rather than being analyzed under a general negligence standard.

The Special Master correctly recognized there is no separate Alabama tort for negligence per se (ECF No. 2271 at 41). *See Prickett v. BAC Home Loans*, 946 F. Supp. 2d 1236, 1247 (N.D. Ala. 2013) ("negligence per se is merely a subsidiary doctrine of negligence whereby a party is considered negligent as a matter of law because it acted in violation of a statute which was designed to prevent the type of harm that occurred."). The Special Master recommended in his

[9] The 7 other states are Arizona, Nebraska, New Mexico, Oregon, Rhode Island, Utah and Wisconsin (ECF No. 2315 at 10). The current briefing is not sufficient to resolve those claims. Philips does not object to the R&R with respect to the viability of negligence per se claims under Minnesota and Tennessee law.

discussion that the motion to dismiss the negligence per se claim under Alabama law be granted (ECF No. 2271 at 43), but Alabama was inadvertently omitted from the actual recommendation (ECF No. 2271 at 158). Respironics' motion to dismiss the Alabama negligence per se claim will be granted with prejudice.

"Under Arkansas law, the violation of a statute is only evidence of negligence and does not constitute negligence per se." *Cent. Oklahoma Pipeline, Inc. v. Hawk Field Servs., LLC*, 2012 Ark. 157, 400 S.W.3d 701, 712 (2012) (citing *Shannon v. Wilson*, 329 Ark. 143, 947 S.W.2d 349 (1997)). *Accord Hammett v. Portfolio Recovery Assocs., LLC*, No. 4:21-CV-00189-LPR, 2022 WL 3370912, at *35 (E.D. Ark. Aug. 16, 2022) ("The Arkansas Supreme Court has held fast to its insistence that 'the violation of a statute is only evidence of negligence and does not constitute negligence per se.'"); *Dudley Flying Serv., Inc. v. AG Air Maint. Servs., Inc*., No. 3:13-CV-00156-KGB, 2015 WL 1564960, at *7 (E.D. Ark. Apr. 8, 2015) (noting that the plaintiff "correctly abandon[ed]" a negligence per se claim). Respironics' motion to dismiss the negligence per se claim under Arkansas law will be granted with prejudice.

"[U]nder Maine's common law[,] the violation of a safety statute is merely evidence of negligence, not negligence per se." *Elliott v. S.D. Warren Co*., 134 F.3d 1, 5 (1st Cir. 1998) (citing *French v. Willman*, 599 A.2d 1151, 1152 (Me. 1991); *Dongo v. Banks*, 448 A.2d 885, 889–90 (Me. 1982)). The Special Master observed that Maine negligence per se actions may be viable if the statute they are based upon allows for a private right of action (ECF No. 2271 at 44). The Special Master did not identify the applicable statute that creates a private right of action in this case. Respironics' motion to dismiss the negligence per se claim under Maine law will be granted without prejudice to plaintiffs' opportunity to plead a viable claim.

The court adopts the reasoning of the R&R with respect to dismissal of the negligence per se claim under Alabama law. The court does not adopt the R&R with respect to Arkansas and Maine law, and Respironics' motion to dismiss the negligence per se claims under Arkansas and Maine law will be granted. As noted above, the dismissal will be with prejudice under Arkansas and Alabama law and will be without prejudice under Maine law. The Special Master may address Respironics' challenges to negligence per se claims under the other 7 states' laws, if necessary, in considering a renewed motion to dismiss.

2. Negligent misrepresentation (Minnesota)

Respironics objects to the recommendation that its motion to dismiss the negligent misrepresentation claims for personal injuries under Minnesota law be denied. In *In re Allergan Biocell Textured Breast Implant Products Liability Litigation*, 537 F. Supp. 3d 679 (D.N.J. 2021) (discussing Minnesota law), the court explained:

> In Minnesota,
>
> > One who, in the course of his business, profession or employment, or in a transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information.
>
> *Bonhiver v. Graff*, 311 Minn. 111, 248 N.W.2d 291, 298 (1976) (citing Restatement, Torts 2d, Tent. Draft No. 12, § 552). "[T]he scope of a negligent misrepresentation claim" is limited "to a commercial or business setting with consequent pecuniary loss," and does not extend to "medical bills." *Forslund v. Stryker Corp.*, No. 09-2134 (JRT/JJK), 2010 WL 3905854, at *6, 2010 U.S. Dist. LEXIS 104227, at *19–20 (D. Minn. Sept. 30, 2010) (citing *id.*) (dismissing the plaintiff's negligent misrepresentation claim for damages resulting from the defendant's medical implant in the plaintiff's body). Plaintiffs' claims are analogous to that in *Forslund*, and should be dismissed under Minnesota law.

Id. at 737. Recently, in *In re Recalled Abbott Infant Formula Products Liability Litigation*, No. 22 C 4148, 2023 WL 3585639, at *9–10 (N.D. Ill. May 22, 2023), the court rejected the plaintiffs' argument that this theory was an open issue and held that the negligent misrepresentation claim must be dismissed because personal injury damages are not recoverable for negligent misrepresentation under Minnesota law. *Id.* at *9-10 (citing *Forslund* for the proposition that the Minnesota Supreme Court has not recognized negligent misrepresentation claims involving allegations of physical harm and rejecting the invitation to create a novel tort under Minnesota law).

The court does not adopt the R&R on this issue (ECF No. 2271 at 61) and will grant Respironics' motion to dismiss the negligent misrepresentation claim under Minnesota law with prejudice.

3. Claims implicating a manufacturing error – Trilogy EVO

Respironics objects to the recommendations that its motion to dismiss the negligent manufacturing claim (count VIII) and express warranty claim (count X) be denied. Respironics asserts two overlapping arguments. First, Respironics asserts that the selection of PE-PUR foam is a design defect covered by count III—not a manufacturing defect. Second, Respironics argues that, at oral argument, plaintiffs conceded that the only manufacturing error alleged in the complaint relates to the Trilogy EVO device, which is not part of this MDL. (ECF No. 2130 at 6, 22-26).

In the R&R, the Special Master explained that plaintiffs (and this court) may not unilaterally expand the scope of an MDL (ECF No. 2271 at 150-52). The initial transfer order involved devices recalled on June 14, 2021 (ECF No. 1 at 2). The Trilogy EVO device was not included

in the June 14, 2021 recall, but was part of a subsequent recall (ECF No. 2271 at 150-52). The Special Master, accordingly, recommended dismissal of plaintiffs' strict liability – manufacturing defect claim (count IX). Plaintiffs did not object to that recommendation and it will be adopted by the court.

The negligent manufacturing claim in count VIII is subject to the same flaw, i.e., it involves a device (the Trilogy EVO) that is not within the scope of this MDL. The Special Master concluded that the allegations in count VIII were sufficient to survive a motion to dismiss (ECF No. 2271 at 136-39). In the master PI complaint, however, the only nonconclusory allegation about negligent manufacturing involves the Trilogy EVO device. (ECF No. 834 ¶ 455) ("Specifically, Respironics used defective, incorrect and non-specified PE-PUR, raw foam product, not intended for use in the Recalled Devices, to manufacture some of the Recalled Devices including certain recalled Trilogy EVO ventilators."). The court concludes that plaintiffs failed to plead a cognizable negligent manufacturing claim about any product within the scope of the MDL.

With respect to the express warranty claim (count X), Respironics argues, in essence: (1) the only claim within the scope of the warranty is a manufacturing error; and (2) the only manufacturing error involves the Trilogy EVO device. Plaintiffs contest the first premise and argue that the warranty more broadly covers workmanship and materials in accordance with product specifications. The Special Master recommended that the nature of the defect and scope of the warranty be determined after discovery (ECF No. 2271 at 119-24).[10] The court agrees with and adopts the recommendation on count X, with the proviso that the express warranty claim cannot be based on the Trilogy EVO because that device is not part of this MDL.

[10] The Special Master also concluded that the issue whether enforcement of the warranty's two-year limitations period would be unconscionable could not be resolved at the motion to dismiss stage.

The Special Master's recommendation at count VIII will not be adopted and his recommendations at counts IX and X will be adopted. Respironics' motion to dismiss counts VIII and IX will be granted, without prejudice to plaintiffs' ability to plead a viable negligent manufacturing or strict liability manufacturing defect claim involving a product within the scope of this MDL. Respironics motion to dismiss count X will be denied.

4. Pennsylvania law – comment k

Respironics objects to the recommendation that the strict liability claim based on a design defect under Pennsylvania law should survive. Respironics argues that the Pennsylvania Supreme Court would categorically bar such claims with respect to prescription medical devices.

Pennsylvania has adopted the Restatement (Second) of Torts § 402A and comment k. Pennsylvania has adopted "a blanket approach applying comment k to preclude strict-liability design-defect claims for all **prescription drugs**." *Lance v. Wyeth*, 85 A.3d 434, 442 n.11 (Pa. 2014) (citing *Hahn v. Richter*, 673 A.2d 888, 889 (Pa. 1996)) (emphasis added). The dispute is whether the Pennsylvania Supreme Court would extend comment k to the prescription medical devices at issue in this case. The Pennsylvania Supreme Court has not directly resolved the issue and the predictions of the numerous other courts to address the issue are split. *See Cohen v. Johnson & Johnson*, 634 F. Supp. 3d 216, 226-29 (W.D. Pa. 2022) (collecting decisions). The Special Master ably summarized the competing positions, concluded that Pennsylvania would not impose a categorical bar on strict liability claims against medical device manufacturers, and recommended that the motion to dismiss be denied (ECF No. 2271 at 147-49).

Respironics' asserts that this court should adhere to its prior decisions in *Killen v. Stryker Spine*, No. CIV.A. 11-1508, 2012 WL 4498865, at *3 (W.D. Pa. Sept. 28, 2012) (Conti, J.), and

Kline v. Zimmer Holdings, Inc., No. CIV.A. 13-513, (W.D. Pa. June 27, 2013) (Conti, J.). In those cases, the parties did not ask this member of the court to determine whether comment k applies to design defect claims against medical device manufacturers.[11] Both *Killen* and *Kline* involved R&Rs prepared by a magistrate judge. In *Killen,* the objection presented to this member of the court was whether Pennsylvania law precludes strict liability claims alleging a manufacturing defect. *Killen*, 2012 WL 4498865, at *3. This court noted there are competing authorities and concluded that "comment k's exemption from strict liability does not extend to manufacturing defects." *Id.* at *4. The defendant's motion to dismiss was denied. In *Kline*, the plaintiffs did "not argue that comment k does not apply to prescription medical devices." *Kline,* 2013 WL 3279797, at *4. The focus of the magistrate judge's R&R in *Kline* was whether comment k would be extended to manufacturing defect claims. *Id*. The magistrate judge concluded that a manufacturing defect claim was not barred (citing *Killen*). In *Kline*, neither party filed objections to the R&R. In sum, even if there were no subsequent developments in Pennsylvania law, this court did not specifically analyze or opine in *Killen* and *Kline* on whether the Pennsylvania Supreme Court would extend comment k to design defects in medical devices.

The court agrees with the Special Master that the decisions of the Pennsylvania Supreme Court indicate a reluctance to impose a categorical exemption from strict liability for medical devices (ECF No. 2271 at 148). In *Tincher v. Omega Flex, Inc*., 104 A.3d 328 (Pa. 2014), the Pennsylvania Supreme Court explained:

> [A] plaintiff pursuing a cause upon a theory of strict liability in tort must prove that the product is in a "defective condition." The plaintiff may prove defective condition by showing either that (1) the danger is unknowable and unacceptable to the average or ordinary consumer, or that (2) a reasonable person would

[11] In both cases, a design defect strict liability claim was raised and the magistrate judges recommended, without analysis, that those claims be dismissed, *see Killen*, 2012 4498865 at *5; *Kline*, 2013 WL 3279797 at *6, but neither plaintiff filed objections to those recommendations.

> conclude that the probability and seriousness of harm caused by the product outweigh the burden or costs of taking precautions.

Id. at 335. The court articulated a general presumption that strict liability principles apply to all products:

> No product is expressly exempt and, as a result, the presumption is that strict liability may be available with respect to any product, provided that the evidence is sufficient to prove a defect. *See* RESTATEMENT (2D) OF TORTS § 402A cmt. b (cause of action in strict liability "cover[s] the sale of **any product** which, if it should prove to be defective, may be expected to cause physical harm to the consumer or his property")

Id. at 382 (emphasis added in *Tincher*).[12]

The text of comment k does not infer a blanket exemption for all medical devices. The commentary states: "There are **some** products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." Restatement (Second) of Torts § 402A cmt. k (1965) (emphasis added). The commentary explains that certain qualifications may apply, including the product is "properly prepared and marketed, and proper warning is given, where the situation calls for it." *Id.* The rationale for the exemption from strict liability is that the manufacturer "has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." *Id.* Viewed in the light most favorable to plaintiffs, the instant record does not conclusively establish that the devices at issue meet the qualifications for the comment k exemption.

The court agrees with the Special Master that the wisest course is to deny Respironics' motion to dismiss and permit discovery on this theory. *See Cohen*, 634 F. Supp. 3d at 228 (concluding that "the extension of comment k to bar strict liability claims may only apply as to

[12] The Pennsylvania Supreme Court has not overruled *Hahn*. In *Lance*, however, the Pennsylvania Supreme Court observed "the truncated analysis in the *Hahn* line offers a poor foundation for extrapolation." *Lance*, 85 A.3d at 452 n. 21.

certain medical devices and only when as evaluated on a case-by-case basis and only after consideration of the full and developed factual record.").[13]

Respironics argues that this court cannot expand the liability provided by state law, citing the "well-established principle that where 'two competing yet sensible interpretations' of state law exist, 'we should opt for the interpretation that restricts liability, rather than expands it, until the Supreme Court of [that state] decides differently." *Travelers Indem. Co. v. Dammann & Co*., 594 F.3d 238, 253 (3d Cir. 2010) (citations omitted). That principle is difficult to apply to the circumstances of this case. Pennsylvania has adopted a general presumption that § 402A liability exists for all products. *Tincher*, 104 A.3d at 382. The issue is whether the exclusion from liability in comment k should be applied to the devices at issue. Respironics is asking this court to recognize the Pennsylvania Supreme Court would interpret comment k in the manner requested by it. *See Moultrie v. Coloplast*, No. 18-231, 2020 WL 1249354 (W.D. Pa. Mar. 16, 2020) ("extending comment k to medical devices is a matter that should be addressed by the Pennsylvania General Assembly or the Pennsylvania Supreme Court").

In sum, the court adopts the Special Master's recommendation that the strict liability – design defect claim under Pennsylvania law should not be dismissed.

[13] There are numerous reasons for caution. In *Lance*, the Pennsylvania Supreme Court observed that comment k is often regarded as "unintelligible." *Lance*, 85 A.3d at 451. The text of comment k specifically refers to drugs, but not medical devices. In *Ebert v. C.R. Bard, Inc*., 2021 WL 2656690 at *3 (3d Cir. 2021), the court observed that negligent design claims involving prescription drugs involve a unique context due to questions about whether FDA would approve a new "design." The court notes that, in this case involving medical devices subject to the Medical Device Act's express preemption provision, 21 U.S.C. § 360k, compliance with FDA's approval may implicate preemption issues. In *Ebert*, the court recognized that negligent design and strict liability claims involving medical devices implicate unresolved and important issues of Pennsylvania law that the Pennsylvania Supreme Court is best positioned to answer and certified two questions to that court. *Id.* at *4. Unfortunately, that case settled before the certified questions were resolved by the Pennsylvania Supreme Court. *Ebert*, No. 20-2139, Order Nov. 10, 2021 (ECF No. 53).

5. Scope of the personal injury master complaint

The Special Master recommended dismissal of consumer protection claims because the laws of 13 states do not give rise to claims for personal injury (ECF No. 2271 at 76-85). Plaintiffs do not challenge that recommendation, but ask the court to clarify that the dismissal applies only to personal injury claims and not to accompanying claims for economic loss for those who opt out of the economic loss settlement (ECF No. 2313 at 16).

As Respironics correctly points out, the parties agreed on an approach by which personal injury, economic loss, and medical monitoring claims were separated into three master complaints. Plaintiffs may not pursue economic loss claims through the Master PI complaint. The analysis of the Master PI complaint does not affect any economic loss claims, which are governed by a separate master complaint. The parties shall meet and confer about how those who opt out of the economic loss settlement may assert their claims for economic loss and shall file their recommendations with the court.

III. Conclusion

In accordance with the foregoing, the court concludes as follows:

A. (ECF No. 2312) Plaintiffs' motion to modify and/or clarify the R&R will be granted in part, in that plaintiffs will be given leave to file an amended personal injury master complaint within 14 days of this opinion and order, limited to claims addressed in the R&R and this opinion and which were not expressly dismissed with prejudice;

B. (ECF No. 2313) Plaintiffs' objections to the R&R will be granted in part, in that plaintiffs will be given leave to file an amended personal injury master complaint to address the deficiencies identified in the R&R and this opinion; and

C. (ECF No. 2315) Respironics' objections to the R&R will be granted in part and denied in part, as follows:

1. The motion to dismiss the negligence per se claims under Alabama and Arkansas law will be granted with prejudice, and the motion to dismiss under Maine law will be granted without prejudice;
2. The motion to dismiss the negligent misrepresentation claim under Minnesota law will be granted with prejudice;
3. The motion to dismiss the negligent manufacturing and strict liability – manufacturing defect claims will be granted without prejudice;
4. The motion to dismiss the express warranty claim will be denied; and
5. The motion to dismiss the strict liability – design defect claim under Pennsylvania law will be denied.

The Special Master's R&R is rejected in part, as specifically set forth in this opinion, and is adopted in all other respects, as supplemented in this opinion. Respironics' motion to dismiss the Master PI complaint (ECF No. 1345) is granted in part and denied in part.

Plaintiffs may file an amended master PI complaint on or before February 12, 2024. Respironics must file its response to an amended master PI complaint on or before February 26, 2024.

An appropriate order will be entered.

BY THE COURT:

/s/ Joy Flowers Conti
Joy Flowers Conti
Senior United States District Court Judge